

Homeland Security & Vaccine Injury Compensation Briefing Paper



What is the Vaccine Injury Compensation Program? The National Childhood Vaccine Injury Act of 1986, Public Law 99-660, was a landmark vaccine safety and compensation law, passed by Congress after five years of effort by the National Vaccine Information Center, the American Academy of Pediatrics, and several vaccine manufacturers.

Physician organizations and vaccine manufacturers were seeking fewer lawsuits and they asserted that this would help insure the availability of vaccines and result in reduced prices.

Parents were seeking a less expensive, less time consuming and emotionally draining alternative to a lawsuit. When the law was passed, parents who had pending lawsuits made a choice between the VICP and continuing their law suit. NVIC insisted on preserving the right to go to court if the VICP ruled against them or the award was not sufficient to care for the injured child.

What other provisions were part of the law? Parents fought hard to have safety provisions as part of the law in an effort to prevent other children from suffering a vaccine injury or death.

Compensation without prevention was not acceptable.

1. *All doctors who administer vaccines must report vaccine reactions to federal health authorities.* The Vaccine Adverse Events Reporting System (VAERS) was created as a centralized reporting system for vaccine adverse events.
2. *All doctors are required to record vaccine reactions in the patient's permanent medical record,* in an effort to prevent a child from being revaccinated after a previous reaction.
3. *Doctors are required to keep a record of the date, manufacturer's name and lot number of the vaccines given,* making it easier to obtain that information and assist in identifying especially reactive lots of vaccine.
4. *Doctors are required to provide parents with written information prior to delivery of the vaccinations,* in an effort to help parents make better-informed decisions.
5. *The Federal Government is required to promote the improvement of existing vaccines and the development of safer vaccines;* so fewer children would suffer an adverse event.

How is this connected to Homeland Security? The VICP has a very short statute of limitations (time in which to file a claim), of 3 years for a vaccine injury and 2 years for a death resulting from a vaccination. In the past ten years autism has increased by 500% in most states and some parents associate their child's autism with an MMR vaccine reaction or with Thimerosal, a preservative used in some vaccines for many years. Thimerosal is a mercury derivative (a known neuro-toxin) used in killed and recombinant vaccines to prevent the growth of bacteria in multi-dose vials. In 1999 the government recommended drug companies remove Thimerosal from vaccines and produce single-dose vials, which would not require a preservative.

A diagnosis of autism is very rarely made in time for a child to qualify for the VICP. This has led to a large number of lawsuits that are outside of the VICP that are in state court. Most states have ruled against these cases due to the jurisdictional issue.

On November 13, 2002, the Homeland Security Bill was passed by the House of Representatives and sent to the Senate. Originally intended to set up a new Department of Homeland Security, the 484-page bill also provided for the biggest reorganization in government since 1947. The last four sections of the bill, (1714-1717) shielded the pharmaceutical industry from lawsuits for injuries caused by FDA-approved vaccines, such as mercury containing pediatric vaccines associated with the development of autism.

Senators Lieberman, Daschle and Byrd proposed an amendment to strike out the vaccine injury liability bailout but it was voted down 47-52. Reports have come out of last minute deals between the White House and rebellious republicans (Senators Snowe, Collins and Chafee) who threatened to vote for the Lieberman amendment. Promises were made that in the new Congress a bill would be passed that would allow existing lawsuits to continue but would bar all future lawsuits.

After much debate the Homeland Security Bill passed the Senate. The four-day debate was covered live on C-Span as Democrats and Republicans squared off on this last minute provision that really had nothing to do with Homeland Security. Articles ran on the front pages of major newspapers and headlined the evening news.

Why do we need to preserve the right to bring a lawsuit when we have the VICP? Children are required by law to be vaccinated before entering daycare, school or college. This is a medical procedure that carries a risk of injury or death and is performed on a healthy individual. There is great debate in the scientific community about which vaccines cause injuries and what those injuries are. It is going to take a long time for science to find all the answers. In the meantime, if even a small percentage of children are injured by mercury, the MMR or any other vaccine that our government requires parents to use, then those children should be entitled to compensation and fair treatment within the system.

It would be the greatest injustice to require vaccination by law, knowing that some children will be permanently brain-damaged or even die as a result and then to single out these children and their parents to taking away their right to common law protection from negligence or unreasonably dangerous products, and making them the only group who do not have the right to go to court. That is hardly real justice, nor good social policy.

The tort system serves to deter negligence and helps augment regulatory incentives for safety. Without the threat of a lawsuit if the VICP does not handle cases fairly or adequately, there is no incentive for drug companies to make their vaccines as safe as possible. The drug companies end up with a ready-made market and no liability.

What other provisions of the Homeland Security Act are troubling? Section 304 of the bill removed from the states their historic control over public health laws, including vaccination laws, and handed it over to federal health officials. This section allows the Secretary of DHHS to issue a "declaration" after concluding that "an actual or potential bioterrorist incident" or "other potential public health emergency" warrants the administration of "a substance or substances" to "individuals during the effective period of the declaration." The law provides for no exemptions to vaccination or medication and is expected to override state public health and vaccine laws which currently provide medical and/or religious exemptions to vaccination for school entry. This federal law also does not preclude the use of the U.S. military to enforce the administration of vaccines or other "substances" to individuals as ordered by the Secretary of DHHS.



The Homeland Security Bill also eroded laws preventing the federal government from conducting the people's business in secrecy, while creating new opportunities for federal employees to look into the private lives of their fellow citizens. Title 2 of the bill gives federal employees unchecked surveillance power to access and track every American's email, internet use, travel, credit card purchases, phone and bank records without a court order.

The public's right to know how government operates was also severely curtailed in the bill with Section 214 gutting the Freedom of Information Act (FOIA), which has allowed the media and private citizens to obtain documents and transcripts of federal health agency meetings such as the FDA and CDC Advisory Committees which regulate vaccines and make vaccine policy.

What is the current status of Homeland Security revisions? On January 10, 2003, Senators Olympia Snowe (R-Maine), Susan Collins (R-Maine), and Lincoln Chafee (R-R.I.) announced that they had reached an agreement with Senate leadership to eliminate the thimerosal protection rider.

The agreement also calls on the Senate to consider and pass comprehensive reforms to the Vaccine Injury Compensation program in the next six months which could lead to a removal of lawsuits from the VICP if the award is not adequate or the case is lost.

These changes were included in the Omnibus Appropriations Bill that passed on February 14, 2003.

Attempted Legislative Changes: NVIC worked hard for the passage of a compensation program and we have continued to serve as the consumer watchdog on the implementation and use of the program. As of 12/31/02 there have been 7580 claims filed. Awards total \$1.4 Billion while nearly 2 out of 3 claimants lose their case.

NVIC has been a staunch critic of the way the program operates and has worked hard for administrative and legislative changes. Beginning in 1999, Congressman Dan Burton, Chairman of the House Government Reform Committee investigated problems in the VICP. A number of issues were identified that led to the introduction of a bill in February 2002 by Congressman Dan Burton (R-IN) and Congressman Henry Waxman (D-CA). The legislative reforms proposed by Burton/Waxman included:

- Extending the statute of limitations for filing a petition in the Vaccine Injury Compensation Program to six years and establishing a two-year window for families to file a petition if they were previously excluded from the Program by the existing statute of limitations.
- Increasing the compensation for vaccine-related deaths to \$300,000;
- Increasing the compensation for lost earnings;
- Including compensation for the costs of family counseling and creating a guardianship;
- Including payment of interim attorneys fees and costs while a case is under review.

In April 2002, Senator Bill Frist (R-TN), introduced a bill that would eliminate all class action vaccine lawsuits, eliminate loss of consortium claims, remove all state cases into federal court, not allow interim attorney fees, not allow a one-time look back provision, and provide the government alternate causes to help them disprove causation.

Neither of these two bills passed but portions of the Frist bill ended up in the Homeland Security Act. All the more reason to suspect that Senator Frist will attempt to give the drug companies an "exclusive remedy" in the compensation program.